510(k) Summary
Lucent® Magnum+

510(k) Number K081711 (pg 1 of 2)

Manufacturer Identification

Submitted by: Spinal Elements, Inc.
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SEP 1 1 2008

Contact Information: Kerri DiMartino
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Date Prepared: September 3, 2008

Device Identification

Proprietary Name	Lucent® Magnum+
Common Name	Vertebral Body Replacement; Intervertebral Body Fusion Device
Device Classification	21 CFR 888.3060 (spinal intervertebral body fixation orthosis); 21CFR 888.3080 (orthosis, spinal intervertebral fusion)
Proposed Regulatory Class	Class II
Device Product Code	MQP; MAX

Device Description

Spinal Elements' Lucent Magnum+ device is composed of a main device body and fixation screws. The main device body is generally oval-shaped with various holes throughout its geometry. The superior and inferior surfaces of the device have engagement members to prevent migration once surgically positioned. The main implant body has holes through it that allow for the passage of bone screws that affix to bone to help prevent migration.

Devices are available in a multitude of sizes. Device bodies are made from either titanium alloy (Ti-6Al-4V), conforming to ASTM F 136 or ISO 5832-3, or polyetheretherketone (PEEK-Optima®), conforming to ASTM F 2026. Screws are made from titanium alloy (Ti-6Al-4V), conforming to ASTM F 136 or ISO 5832-3. All implants are intended for single use only and should not be reused under any

circumstances. Components from this system should not be used in conjunction with components from other systems.

Intended Use of the Device

When used as a vertebral body replacement:

When used as a vertebral body replacement, the device is intended for use in the thoracic and/or thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacer can be packed with allograft or autograft.

When used as an intervertebral body fusion device:

When used as an intervertebral body fusion device, the device is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). This device is intended to be used with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

Substantial Equivalence

The Lucent Magnum+ device was shown to be substantially equivalent in indications for use, general design features, function, and materials to the following predicates: Lucent® by Spinal Elements (K071724), Lucent® Magnum by Spinal Elements (K073348), and STALIF TT™ by Surgicraft (K073109).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 12 2011

Spinal Elements, Incorporated
% Ms. Kerri DiMartino
Regulatory Affairs Specialist
2744 Loker Avenue West, Suite 100
Carlsbad, California 92010

Re: K081711
Trade/Device Name: Lucent® Magnum+
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD, MQP
Dated: June 13, 2008
Received: June 17, 2008

Dear Ms. DiMartino:

This letter corrects our substantially equivalent letter of September 11, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081711

Device Name: Lucent® Magnum+

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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